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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,790	10/24/2001	Daniel A. Keys	2064-181	7203

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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	3

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,790	KEYS ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 5-9, and 26-31 drawn to a method for enhancing the dynamic range of an assay of the presence, absence, activity or concentration of two or more target analytes in one or more samples , classified in class 435, subclass 7.1.

II. Claim 2, drawn to a method for enhancing the dynamic range of an assay of the presence, absence, activity or concentration of two or more target analytes in one or more samples, classified in class 436, subclass 63.

III. Claims 3 and 4 drawn to a method for enhancing the dynamic range of an assay of the presence, absence, activity or concentration of two or more target analytes in one or more samples, classified in class 436, subclass 164.

IV. Claims 32, 36-42 and 59-62, drawn to an apparatus for enhancing the dynamic range of an assay of the presence, absence, activity or concentration of two or more target analytes in one or more samples, classified in class 422, subclass 82.07.

V. Claim 33, drawn to an apparatus for enhancing the dynamic range of an assay of the presence, absence, activity or concentration of two or more

target analytes in one or more samples, classified in class 422, subclass 104.

VI. Claims 34 and 35, drawn to an apparatus for enhancing the dynamic range of an assay of the presence, absence, activity or concentration of two or more target analytes in one or more samples, classified in class 435, subclass 808.

2. Inventions I and II are independent and distinct inventions. Invention II requires at least one of the target analytes, the computer system causes the CCD camera detector to detect light signal cumulatively until a total detected light signal is obtained that is within the known dynamic range of the assay for the target analyte; and the total detected light signal is used to determine the presence, absence, activity or concentration of the target analyte and Invention I does not require these limitations.

3. Inventions I and III are independent and distinct inventions. Invention III requires the computer system to cause the CCD camera detector to detect light signal discontinuously at more than one time interval so that a detected light signal is obtained that is within the known dynamic range of the assay for the target analyte; and the detected light signal within the known dynamic range of the assay for the target analyte is used to determine the presence, absence, activity or concentration of the target analyte and Invention I does not require these limitations.

4. Inventions I and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as

claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another materially different apparatus such as the apparatus of Invention V.

5. Inventions I and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention I.

6. Inventions I and VI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention I.

7. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention II requires at least one of the target analytes, the computer system causes the CCD camera detector to detect light signal cumulatively until a total detected light signal is obtained that is within the known dynamic range of the assay for the target analyte; and the total detected light signal is used to determine the presence,

absence, activity or concentration of the target analyte whereas, Invention III requires the computer system to cause the CCD camera detector to detect light signal discontinuously at more than one time interval so that a detected light signal is obtained that is within the known dynamic range of the assay for the target analyte; and the detected light signal within the known dynamic range of the assay for the target analyte is used to determine the presence, absence, activity or concentration of the target analyte.

8. Inventions II and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention I.

9. Inventions II and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention I.

10. Inventions II and VI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as

claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention I.

11. Inventions III and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention I.

12. Inventions III and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention II.

13. Inventions III and VI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention I.

14. Invention IV and V are independent and distinct inventions. Invention V requires at least one of the target analytes, the computer system causes the CCD camera detector to detect light signal cumulatively until a total detected light signal is obtained that is within the known dynamic range of the assay for the target analyte; and the total detected light signal is used to determine the presence, absence, activity or concentration of the target analyte and Invention IV does not require these limitations.

15. Inventions IV and VI are independent and distinct inventions. Invention VI requires the computer system to cause the CCD camera detector to detect light signal discontinuously at more than one time interval so that a detected light signal is obtained that is within the known dynamic range of the assay for the target analyte; and the detected light signal within the known dynamic range of the assay for the target analyte is used to determine the presence, absence, activity or concentration of the target analyte and Invention does not require these limitations.

16. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention V requires at least one of the target analytes, the computer system causes the CCD camera detector to detect light signal cumulatively until a total detected light signal is obtained that is within the known dynamic range of the assay for the target analyte; and the total detected light signal is used to determine the presence, absence, activity or concentration of the target analyte whereas, Invention VI requires the computer system to cause the CCD camera detector to detect light signal

discontinuously at more than one time interval so that a detected light signal is obtained that is within the known dynamic range of the assay for the target analyte; and the detected light signal within the known dynamic range of the assay for the target analyte is used to determine the presence, absence, activity or concentration of the target analyte.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: the target analyte in claims 9 and 42; claims 10-25 and 43-58 includes limitations dependent upon which species in claims 9 and 42 is finally elected by Applicant.

A). enzyme

B). drug or metabolite

C). a co-factor

D). a receptor

E). a receptor ligand

F). a hormone

G). a cytokine

H). a blood factor

I). a virus

J). an antigen

K). a steroid

L). an antibody

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 1, 5-9, 26-31 and claims 32, 36-42 and 59-62 are generic. Claims 10-25 and 43-58 are subject to species election.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
February 21, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/21/03